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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,479	05/10/2006	Steffen Goletz	GULDE-63	4918

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER
GUSSOW, ANNE

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
07/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,479	GOLETZ ET AL.	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-83,85-117 and 122-129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-83,85-117 and 122-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 87, 88, 95, 96, 102, 113 have been amended.

Claims 1-78, 84, and 118-121 have been cancelled.

Claims 122-129 have been added.

2. Claims 79-83, 85-117, and 122-129 are under examination.

3. The following office action contains NEW GROUNDS of Rejection.

Objections Withdrawn

4. The objection to claim 102 as being in improper dependent form is withdrawn in view of applicant's amendment to the claim.

5. The objection to claims 113 and 115 as being dependent upon a canceled claim is withdrawn in view of applicant's amendment to the claim.

Rejections Withdrawn

6. The rejection of claims 88 and 96 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrase "at least one sequence of sequences" is withdrawn in view of applicant's amendment to the claims.

7. The rejection of claims 88 and 96 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment to the claims.

8. The rejection of claims 119 and 121 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's cancellation of the claims.

9. The rejection of claims 79-83, 85-101, 103-118, and 120 under 35 U.S.C. 101 as being directed to non-statutory subject matter is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained/NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. The rejection of claims 80 and 90 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrase "a combination of SEQ ID No. 33 and SEQ ID No. 35" is maintained.

Applicant's arguments filed March 19, 2009 have been carefully considered by the examiner but they are deemed not to be persuasive. The response states that as explicitly stated under paragraphs [0055]-[0057] of the published application, the recognition molecules comprise a combination of "triplet sequences with antibody

framework sequences," wherein "the amino acid sequences corresponding to FRH1, FRH2, FRH3 and FHR4 in Table 2 for the variable heavy chain and the amino acid sequence corresponding to FRL1, FRL2, FRL3 and FRL4 in Table 2 for the variable light chain [comprise] the amino acid sequences of the triplet sequences 1 and 2 with SEQ ID Nos. 1 to 12 corresponding to the corresponding CDR regions of the antibodies." It is further taught that "SEQ ID Nos. 32 and 33 correspond to amino acid sequences with preferred framework sequences for the variable heavy chain" and that "the amino acid sequences SEQ ID Nos. 34 and 35 correspond to amino acid sequences with preferred framework sequences for the variable light chain." To this end, the specification explicitly teaches that the combination comprising SEQ ID NO. 32 and 34 and the combination SEQ ID NO. 33 and 35 are particularly preferred (see response pages 22-23).

In response to this argument, when given the broadest reasonable interpretation the claims read on a composition comprising a portion of SEQ ID No. 33 and a portion of SEQ ID No. 35 in combination. The claim is not clear as to which portion of each sequence is in the composition, nor how the sequences are being combined.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. The rejection of claims 85, 86, 93, 94, 104-107, and 109-112 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

Applicant's arguments filed March 19, 2009 have been carefully considered by the examiner but they are deemed not to be persuasive. The response states that the SK-LC-4 mouse tumor (prevention) model described and referred to in Dr. Danielczyk's Declaration flied October 3, 2008 provides sufficient evidence for the aspects for enablement. In particular, in the mouse tumor model human lung cancer cells were injected prior to an antibody molecule encompassed by the scope of the claimed recognition molecule. This initial treatment was followed by subsequent administration of the antibody. The result shown in Figure 17B of the declaration provides sufficient evidence that, in comparison to a control group which did not receive an antibody, antibody-treated human lung cancer cells could not properly settle and thus form a tumor. This result demonstrates that the antibody is useful in preventing tumor formation. Indeed, the antibody prevented cells from forming a tumor in the mouse model (see response pages 23-25).

In response to this argument, both the Danielczyk declaration and the Cancer Immunology and Immunotherapy (Danielczyk, et al.) article support the administration of the claimed antibody for the treatment, diagnosis or reduction of cancer. Each of the examples provided by applicant requires the presence of cancer cells before administration of the antibody. Applicant's comments regarding figure 17B of the declaration provides further support for the treatment of cancer. These experiments do

not provide support for the prophylactic prevention of cancer when cancer cells are not already present in the subject.

Regarding the prediction of cancer, applicant's declaration and Kuemmel document provide support for the diagnosis of cancer. The Kuemmel reference also provides support for the detection of TA-MUC1 being indicative of a favorable prognosis. This evidence does not however provide support for predicting if a subject will develop cancer at some point in the undetermined future. The evidence provided in applicant's specification and in the subsequent declaration and references support the use of the MUC1 antibody for the detection, diagnosis, and treatment of cancer.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

14. Claims 79-83, 85-117, and 122-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed March 19, 2009 has introduced NEW MATTER into the specification. Amended claims 87, 88, 95, and 96 recite a recombinant or synthetic recognition molecule. The response pointed to claims 118-121 and subsequently the sequence disclosure to provide support for the term "synthetic" in the response to the new matter rejection of claims 119 and 121 (see response page 23). The sequence

listing does not provide support for the term "synthetic". Instant claims 87, 88, 95, and 96 now recite limitations, which were not clearly disclosed in the specification, drawings, or claims as originally filed. Such limitations recited in amended claims 87, 88, 95, and 96, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claims 87, 88, 95, and 96 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
June 26, 2009

/Anne M Gussow/
Examiner, Art Unit 1643

/David J Blanchard/
Primary Examiner, Art Unit 1643